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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,716	10/31/2003	H. William Bosch	029318-0977	8372

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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,716	BOSCH ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-41 and 43-108* is/are pending in the application.

4a) Of the above claim(s) *8,15,16,23-27 and 48-108* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-7, 9-14,17-22,28-41 and 43-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/10/08, 01/16/09, 02/24/09, 03/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continuation Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/16/09 has been entered.

Response to Amendment

This Office Action is in response to the amendment submitted on 01/16/2009. Claims 1-3, 5-41, and 43-108 are pending in the applications, with claims 8, 15-16, 23-27, 48-108 having being withdrawn. Accordingly, claims 1-3, 5-7, 9-14, 17-22, 28-41, and 43-47 are being examined on the merits herein.

Receipt of the aforementioned amended claims and Information Disclosure statements is acknowledged and has been entered.

Examiner further acknowledges withdrawal of the Obviousness Double patenting rejection of claims 1, 4-7, 9-12, 14, 18-21, and 28-47 over claims 1-15, 17-20, and 22-41 of application 10/683,154 given that application 10/683,154 is now abandoned.

Applicant's arguments regarding claim 14 has been fully considered. Given that applicant has amended the claims to now exclude ionic and non-ionic surface stabilizers, such rejection is now moot. Thus, the rejection of claims 1-5, 7, 9-14, 18, 21, and 28-41 over Krause in view of Radhakrishnan is hereby withdrawn. As for applicant's arguments that encapsulation means to enclose as in a capsule or container, the Examiner disagrees as Krause did teach that the triamcinolone drug was embedded (i.e. attached) which necessarily means that the drug is sitting in the core center of the particle and thus the particle necessarily coats such drug. As for the particle size, Krause also taught that the particles containing the drug were less than 1 micron further suggesting that the triamcinolone drug would necessarily be less than 1 micron as they were contained inside the particles. Nonetheless, the rejection is hereby withdrawn as applicant has amended their claims to exclude certain stabilizers.

For the foregoing reasons, the rejections of record are hereby withdrawn. However, the following ODP, 112, second paragraph, and 103(a) Non-Final rejections are being made.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-6, and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51, 60-61, and 64 of copending Application No. 12/320431 (hereinafter Bosch US Patent Application No. ‘020). Although the conflicting claims are not completely identical, they are not

patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Bosch '431 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Bosch '431 teaches a broad genus of drug particles. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 12/320431.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5, 11-12, and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-10, 15, and 17 of copending Application No. 12/292092 (hereinafter Wood US Patent Application No. '092). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Wood '092 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Wood '092 teaches a subgenus of beclomethasone dipropionate drug particles.

Consequently, it would have been well within the purview of the skilled artisan to substitute other anti-inflammatory agents such as beclomethasone dipropionate into the composition as they are known equivalents. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 12/292092.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 10-14, 33-36, and 39-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51, 60-61, and 64 of copending Application No. 12/117982 (hereinafter Merisko-Liversidge US Patent Application No. '982) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Merisko-Liversidge '982 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Merisko-Liversidge '982 teaches a subgenus of angiogenesis inhibitor drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances into the composition depending on the targeted

treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 12/117982.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-7, 9, 13-14, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 12/052436 (hereinafter Bosch US Patent Application No. '436). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Bosch '436 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Bosch '436 teaches a broad genus of sterile drug particles. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 12/052436.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5, and 12-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-12 and 19 of copending Application No. 12/051448 (hereinafter Wood US Patent Application No. '448). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Wood '448 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Wood '448 teaches a subgenus of beclomethasone drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other anti-inflammatory agents such as beclomethasone into the composition as they are known equivalents. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 12/051448.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-11, 13-14, 21-22, 28-41, and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-19, and 21-23 of copending Application No. 11/980719 (hereinafter Bosch US Patent Application No. '719) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Bosch '719 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Bosch '719 teaches a subgenus of α-integrin antagonist drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances into the composition depending on the targeted or desired treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11/980719.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-6, 9, 11-14, and 44-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 8, 13-14, and 16-20 of copending Application No. 11/979253 (hereinafter Ryde US Patent Application No. '253). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Ryde '253 are rendered obvious over another as the claimed invention teaches a broad genus of a composition containing a subgenus of triamcinolone drug particles whereas Ryde '253 teaches a subgenus of a low viscosity liquid dosage containing a broad genus of active agent particles. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11/979253.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9, 11-14, 20, 28-31, 33-41, and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5-19 of copending Application No. 11/761900 (hereinafter Liversidge US Patent Application No. '900) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not patentably

distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Liversidge '900 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Liversidge '900 teaches a subgenus of LS104 kinase inhibitor drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances into the composition depending on the targeted or desired treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11/761900.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-11, 13-14, 20-22, 28-32, 33-40, and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-14, 17-19, and 21-23 of copending Application No. 11/436887 (hereinafter Bosch US Patent Application No. '887) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not

patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Bosch '887 are rendered obvious over another as the claimed invention teaches a composition containing a subgenus of triamcinolone drug particles with a broad genus of surface stabilizers whereas Bosch '887 teaches a composition containing a subgenus of α-integrin antagonist drug particles with a subgenus of surface stabilizers. Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances into the composition depending on the targeted or desired treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11/436887.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 5-7, 9-10, and 13-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, 9, and 18-21 of copending Application No. 11/376553 (hereinafter Liversidge US

Patent Application No. ‘553) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Liversidge ‘553 are rendered obvious over another as the claimed invention teaches a composition containing a subgenus of corticosteroid drug particles such as triamcinolone whereas Liversidge ‘553 teaches a composition containing a subgenus of leukotriene receptor antagonist drug particles with a broad genus of corticosteroid. Consequently, it would have been well within the purview of the skilled artisan to add a leukotriene receptor antagonist to the instant composition depending on the targeted or desired treatment. Moreover, given that Liversidge ‘684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11/376553.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-14, 18-21, 28-29, and 39-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 8-9, 11-13, 15-16, 18-20, 24, and 27 of copending Application No. 11/275069 (hereinafter Bosch US Patent Application No. '069) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Bosch '069 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Bosch '069 teaches a subgenus of MAP kinase inhibitor drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances into the composition depending on the targeted or desired treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11/275069.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-12, 14, 18-22, 28-29, 31, 33-41, and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-12, 15-17, and 20-31 of copending Application No. 10/912552 (hereinafter Pruitt US Patent Application No. '552) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Pruitt '552 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Pruitt '552 teaches a subgenus of metaxalone drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances into the composition depending on the targeted or desired treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/912552.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-14, 18-22, 28-29, and 33-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12-24, 30, 34-35, and 38-39 of copending Application No. 10/895405 (hereinafter Ryde US Patent Application No. '405) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Ryde '405 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Ryde '405 teaches a subgenus of sildenafil drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances into the composition depending on the targeted or desired treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/895405.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-14, 17-22, 28-41, and 43-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of copending Application No. 10/768194 (hereinafter Hovey US Patent Application No. '194). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Hovey '194 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Hovey '194 teaches a subgenus of fluticasone drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other anti-inflammatory agents such as fluticasone into the composition as they are known equivalents. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/768194.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-14, 17-22, 28-41, and 43-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 and 36-39 of copending Application No. 10/701064 (hereinafter Bosch US Patent Application No. '064) in view of Liversidge et al. (U.S. 5,145,684). Although the

conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Bosch '064 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Bosch '064 teaches a subgenus of glipizide drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances into the composition depending on the targeted or desired treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/701064.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-14, 17-22, 28-41, and 43-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31, 36-38, and 40 of copending Application No. 10/697703 (hereinafter Bosch US Patent Application No. '703). Although the conflicting claims are not completely

identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Bosch '703 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Bosch '703 teaches a subgenus of nimesulide drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other anti-inflammatory agents such as nimesulide into the composition as they are known equivalents. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/697703.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5, 9, and 13-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/317948 (hereinafter Bosch US Patent Application No. '948). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Bosch '948 are rendered obvious over another as the claimed invention

teaches a subgenus of triamcinolone drug particles whereas Bosch '948 teaches a subgenus of 2-R-(1-(R-(3,5-bi(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other anti-inflammatory agents into the composition as they are known equivalents. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/317948.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-14, 18-22, 28-29, and 33-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-19, and 21-32 of copending Application No. 11928250 (hereinafter Merisko-Liversidge US Patent Application No. '250) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Merisko-Liversidge '250 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Merisko-Liversidge '250 teaches a subgenus of angiogenesis inhibitor drug particles.

Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances into the composition depending on the targeted or desired treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11928250.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-14, 28-29, 33-41, and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-19, and 21-32 of copending Application No. 11/367716 (hereinafter Cooper US Patent Application No. '716) in view of Liversidge et al. (U.S. 5,145,684). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a composition comprising nanoparticulate drug particles of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Cooper '716 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Cooper '716 teaches a subgenus of

statin drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other drug substances depending on the targeted or desired treatment. Moreover, given that Liversidge '684 teaches that such nanoparticles exhibit unexpected bioavailability (see abstract), one of ordinary skill would have indeed found it obvious to formulate various drugs as such coated nanoparticles in order to obtain an enhanced bioavailability. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11/367716.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9-14, 17-22, and 33-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/784900 (hereinafter Cooper US Patent Application No. '900). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a nanoparticulate drug particles comprising crystalline drugs of a size of less than 2000 nm with a surface modifier adsorbed unto the surface thereof. The claimed invention and co-pending application Cooper '900 are rendered obvious over another as the claimed invention teaches a subgenus of triamcinolone drug particles whereas Cooper '900 teaches a subgenus of meloxicam drug particles. Consequently, it would have been well within the purview of the skilled artisan to substitute other anti-inflammatory

agents as they are known equivalents. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/784900.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claim 14 is particularly vague and indefinite given that dependent claim 14 exclude nonionic and ionic surface stabilizers in the composition (i.e. in claim 13) and yet applicant recites addition of ionic and nonionic surface stabilizers such as polaxamers and decanoyl-N-methylglucamide surfactants to the composition (i.e. in claim 14 which incorporates all of the limitation of claim 13). Thus, given that applicant claims non-addition of nonionic surfactants that are supposedly excluded under the consisting transitional language of claim 13, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claim.

As a result of the above inconsistencies, the aforementioned claim is unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art. However, for the purpose of examination, Examiner will construe that the stated ionic and nonionic species set forth in the claims are excluded from the composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-7, 9-14, 17-22, 28-41, and 43-47 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Liversidge et al. (U.S. 5,145,684) in view of Desai et al. (U.S. 5,916, 596).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Liversidge et al. teach dispersible particles consisting essentially of a crystalline drug substance having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective average particle size of less than about 400 nm (instant claims 1 and 5; see abstract and col. 2, lines 3-35 and 38-43). Additionally, Liversidge et al. teach pharmaceutical compositions containing the particles which exhibit unexpected bioavailability and that are useful in treating mammals (see abstract, col. 2, lines 35-37 and 57-60, and col. 3, lines 3-5 and 22-24). Moreover, Liversidge et al. teach that poorly soluble drugs tend to have poor bioavailability and thus tend to be eliminated in the gastrointestinal tract and unsafe for intravenous administration (see col. 1, lines 13-27). Furthermore, Liversidge et al. teach that decreased drug particles tend to have increased rate of dissolution (see col. 1, lines 28-34). Thus, Liversidge et al. sought to provide stable dispersible drug particles in the submicron size range which can be readily prepared, do not flocculate, do not require the presence of a crosslinked matrix, and that are highly desirable in pharmaceutical compositions as they have enhanced bioavailability (see col. 2, lines 22-29). Liversidge et al. also teach that the invention can be made as a stable dispersion wherein the dispersion medium is water (instant claims 7, 9, and 31; see col. 3, lines 45-50) consisting essentially of the liquid dispersing medium and the above-described particles dispersed therein (see col. 2,

lines 44-46). Additionally, Liversidge et al. teach that the particles comprise a drug substance wherein the drug substance exists as a discrete crystalline phase (instant claim 1; see col. 3, lines 32-37). Moreover, Liversidge et al. teach that the invention can be practiced with a wide variety of drug substances especially those that are poorly soluble (see col. 3, lines 38-44). Suitable drug substances can be selected from a variety of classes including anti-inflammatory agents, corticosteroids, antivirals and the like etc...(instant claims 21-22; see col. 3, lines 53-68 and col. 4, lines 1-27; and col. 15, claims 4-5). Moreover, the drug substance as described above have a surface modifier adsorbed on the surface thereof wherein the most useful modifiers are those that physically adhere to the surface of the drug substance but do not chemically bond to the drug and comprise organic and inorganic pharmaceutical excipients including the anionic surfactants such as sodium dodecylsulfate or sodium lauryl sulfate and bioadhesive surfactants such as hydroxypropylcelluose or polyvinylpyrrolidone (instant claims 13-14 and 17-18; see col. 4, lines 34-68 and col. 5, lines 1-19). Liversidge et al. also teach that close to 90% of the particles have an effective average particle size of 400 nm thereby suggesting that the composition also contain other drug substance particle sizes (instant claims 19-20 and 28-29; see col. 5, lines 25-40 and col. 15, claims 2-3). Particularly, Liversidge et al. teach that the concentration of the drug substance may vary from 0.1-60% while the surface modifier can vary from about 0.1 to about 90% with the viscosity of the suspension being less than 1000 cps or less than 1000 mPa-s (instant claims 10-11 and 44-47; see col. 5, lines 64-68; col. 6, lines 1-5 and 25-31; col. 7, lines 10-20; and col. 15, claims 1 and 6). The compositions can include acceptable

carriers for parenteral injection, oral administration in solid or liquid form, for rectal administration and the like (instant claim 6; see col. 7, lines 53-60 and col. 8, lines 10-13).

Liversidge et al. do not specifically teach the drug substance as triamcinolone acetonide. Additionally, Liversidge et al. do not teach addition of at least two surface stabilizers or other drug substances to the composition. Moreover, Liversidge et al. do not teach the redispersibility of the particles or the pharmacokinetic profile of the drug substances including the particular absorption levels and percentages of Tmax, Cmax, AUC or the bioequivalency.

Desai et al. teach compositions containing water insoluble pharmacologically active agents in which the pharmacologically active agents is delivered in suspended coated particles and wherein the composition is redispersible and readily bioavailable (see abstract). Desai et al. was provided to demonstrate that triamcinolone acetonide is a poor soluble drug (instant claims 2-3; see col. 11, lines 1-67, col. 12, 1-67, col. 13, lines 1-67, and col. 14, lines 1-53) and would have been obvious to substitute into the composition of Liversidge et al. to one of ordinary skill since Liversidge et al. teach the use of poorly soluble drugs in his composition. Additionally, Desai et al. teach that such compositions can be formulated in various forms including topical forms (see col. 8, lines 17-22).

Additionally, one of ordinary skill in the art would have found it obvious to add additional surface stabilizers and anti-inflammatory agents such as acetylsalicylate to the composition depending on the desired stabilizing effect and the desired composition. Moreover, it is the position of the Examiner that the composition taught by the cited references would have the properties similar to that of the claimed invention, because the references teach the use of the same claimed surface modifiers and methods of making such particles which would necessarily confer the enhanced pharmacokinetic profiles observed. It is further noted that products of identical chemical composition cannot have mutually exclusive properties and therefore a chemical composition and its properties are inseparable. Thus, if the prior art teaches the identical chemical structure, the properties disclosed and/or claimed by applicant are necessarily present. *In re Spada, 911 F.2d 705,709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).*

It is further noted that In re Best,195 USPQ 430, and In re Fitzgerald, 205 USPQ 594, discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Regarding the redispersibility of the triamcinolone particles, given that Liversidge in view of Desai teach that the particles do possess minute diameters, the Examiner contends that it would be well within the purview of one of ordinary skill in the art to conclude the modified particles of Liversidge are able to redistribute to the lung and liver in view of the teachings of Liversidge et al that the particles do not aggregate or flocculate.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute triamcinolone acetonide as the drug substance into the composition of Liversidge et al. since Liversidge et al. teach that poorly soluble drugs such as triamcinolone would be effective in his invention. Thus, given the teachings of Liversidge and Desai, one of ordinary skill would have been motivated to substitute triamcinolone into the composition of Liversidge with the reasonable expectation of providing a topical composition that is readily bioavailable and a composition that does not aggregate.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

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/S. J. L. /

Examiner, Art Unit 1617

04/07/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617